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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/656,750  | 09/05/2003  | Johnson E. Goode     | 11367.00            | 9063             |
| 27581   | 7590        | 11/09/2006           | EXAMINER            |                  |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARK<br>MINNEAPOLIS, MN 55432-9924 |             |                      |                     | MEHTA, BHISMA    |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3767  |             |                      |                     |                  |

DATE MAILED: 11/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/656,750             | GOODE ET AL.        |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Bhisma Mehta           | 3767                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 September 2006.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed..
- 6) Claim(s) 1-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 11 September 2006 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | Paper No(s)/Mail Date. _____.                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____.                         |

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 157 (line 29 of page 8). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.
2. The drawings were received on September 11 2006. These drawings are not acceptable. Specifically, changes have been made to Figure 3 in the replacement sheet which alter what was shown originally in Figure 3. The addition of the braiding (149) is acceptable as this was in response to the objection that the outer layer having a stainless steel braiding along the first portion and being non-braided along the second portion was not shown in the originally filed Figure 3. However, the alterations such as the changed location of the anchoring band (160), the removal of the solid line adjacent the anchoring band, and the changed location and appearance of the compressible

member are not acceptable. Furthermore, applicant is requested to submit an explanation, in detail, of all changes which are made to the originally filed drawings.

***Specification***

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose what is meant by "the outer layer along the first portion of the shaft being of uniform thickness" and "the outer layer along the second portion of the shaft forms a first lumen portion" as applicant has not clearly described where the first portion and the second portion of the shaft are relative to the various portions of the shaft. It appears, however, that the braided non-deflectable portion (108) which extends from a proximal end (110) to a distal end (112) refers to the first portion and the steerable portion (114) which extends from a proximal end (116) to a distal end (118) refers to the second portion. Therefore, the first portion and the second portion of the shaft need to be clearly defined as to their relationship with the other portions of the shaft.

***Claim Objections***

4. Claim 40 is objected to because of the following informalities: In line 28 of claim 40, it is unclear what the second portion in the phrase "the second portion to a point along..." is referring to as a second portion of the shaft and a second lumen portion have both been established. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 4, 7, 11, 16, 19, 20, and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Koblish (Pub. No. US 2004/0193149).

Koblish discloses a medical therapy delivery device having a shaft (500) with a first portion (504) and a second portion (502). As shown in Figure 3, a deflectable tip (18) extends distally from the second portion and has a tapered portion and a tip lumen (124). In paragraph [0066], Koblish teaches that the tip may include a distal opening and, in Figure 3, the distance between the outer wall and inner wall gradually decreases between the proximal end and the distal end of the tapered portion. The device also includes a manipulator wire (130) that extends through the shaft and a thru lumen tubing (42) having a thru lumen. In Figure 8A, the outer layer of the shaft forms a single shaft lumen having a first lumen portion positioned about the thru lumen tubing and a second lumen portion having a first side wall, a second side wall, and a bottom side wall which position the manipulator wire within the second lumen portion. As to claim 2, the outer layer of the shaft is formed of polyether block amide (polyether polyamide block copolymer). As to claim 4, the tip contains a radio opaque and echo-genic material. As

to claim 7, in paragraph [0052], Koblish discloses the thru lumen tubing as being formed by a PEBA material having a durometer of 72D. As to claim 11, as shown in Figure 3, an anchoring device (630) is positioned along a distal end of the second portion and is fixedly engaged with the manipulator wire (130). Also shown is the manipulator wire (130) that extends through the transition lumen of the transition tubing (536). As to claim 16, in paragraph [0059], Koblish discloses that the thru lumen tubing are free to slide within the shaft during deflection of the second portion of the shaft. As to claim 19, in Figure 8C, Koblish shows the first and second flanges as claimed. As to claim 20, Figure 8C shows the thru lumen tubing (42), the first side wall, the second side wall, and the bottom side wall positioning the transition tubing (536) within the second lumen portion. As to claim 22, the first lumen portion is generally semi-circular in shape and the second lumen portion is generally rectangular in shape.

#### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish in view of Stewart et al (U.S. Patent No. 6,926,669).

Koblish discloses the invention substantially as claimed. Even though Koblish teaches in paragraph [0048] that the polyether block amide outer layer may contain wire

braids to provide torsional stiffness to the shaft, Koblish is silent on the outer layer including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figure 15, Stewart et al show the outer layer of a medical device having a first portion (22) made of a high durometer (such as 72D) polyether block amide with a stainless steel braiding and a second non-braided portion and teach that the braiding provided reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the first portion of the outer layer of Koblish with a high durometer (such as 72D) polyether block amide with a stainless steel braiding as taught by Stewart et al as both Koblish and Stewart et al disclose devices having a deflectable second portion and Stewart et al teach that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Stewart et al teach that the second portion (30) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer reading of the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the transition tubing having a length of approximately one inch in claim 18, the parameter of length is deemed a matter of design choice, well within the skill of the

ordinary artisan, obtained through routine experimentation in determining optimum results.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish in view of Hobot et al (Pub. No. US 2003/0109823).

Koblish discloses the invention substantially as claimed. Even though Koblish teaches a deflectable tip formed of a radio opaque and echo-genic polyether block amide material, Koblish is silent on the polyether block amide material being loaded with jet milled tungsten carbide and having a durometer reading of 35D. Hobot et al disclose a medical device having a deflectable tip (24) made of a polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the polyether block amide tip of Koblish with jet milled tungsten carbide and a durometer reading of 35D as taught by Hobot et al as both Koblish and Hobot et al teach advancing a medical device in blood vessels and Hobot et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced through the blood vessels.

10. Claims 6 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish.

Koblish discloses the invention substantially as claimed. In paragraph [0066], Koblish teaches that the tip may include a distal opening and, in Figure 3, the distance between the outer wall and inner wall gradually decreases between the proximal end and the distal end of the tapered portion. However, Koblish does not disclose the

thicknesses of the walls of the deflectable tip or the diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish in view of Truckai (U.S. Patent No. 5,397,304).

Koblish discloses the invention substantially as claimed. However, Koblish does not disclose the transition tubing being formed of a polyimide material having a durometer reading of 86D. In Figure 2, Truckai shows a steerable medical device having a polyimide transition tubing (58) through which a manipulator wire extends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the transition tubing of Koblish from a polyimide material as taught by Truckai as both Koblish and Truckai disclose steerable devices having a transition tubing through which a manipulator wire extends and Truckai teaches that it would be advantageous to make the transition tubing from polyimide to provide lateral and torsional stiffness to the deflectable tip. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

12. Claims 13-15, 17, 21, 23-26, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish in view of Ponzi (U.S. Patent No. 5,897,529).

Koblish discloses the invention substantially as claimed as discussed above. However, Koblish does not disclose the medical device having a compressible member positioned through which the manipulator wire extends and which is free to move relative to the manipulator wire and the shaft during deflection of the second portion. In Figure 2, Ponzi shows a steerable medical device having a compressible member (44) through which a manipulator wire (42) extends. In lines 14-45 of column 6, Ponzi teaches that the compressible member is anchored at its proximal end and distal end thus allowing it to move freely relative to the manipulator wire and the shaft during deflection. The wire preferably has a diameter ranging from about 0.006 to 0.010 inches. The inner diameter of the compressible member is preferably slightly larger than the diameter of the manipulator wire. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the manipulator wire of Koblish with a compressible member positioned between the distal end of the transition tubing and the anchoring band where the distal end of the compressible member is fixedly engaged with the outer layer so that the compressible member can move freely as taught by Ponzi as both Koblish and Ponzi disclose steerable devices having a compressible member through which a manipulator wire extends and Ponzi teaches that it would be advantageous to have a compressible member to provide flexibility to the deflectable portion of the steerable device. As the limitation of the diameters of the compressible members in claim 14, the parameter of diameters is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of

the transition tubing having a stiffness greater than the compressible member in claim 17, it would be obvious to one having ordinary skill in the art at the time the invention was made that transition tubing of Koblisch would be stiffer than the flexible compressible member of Ponzi as the compressible member is in the second deflectable portion of the shaft. As to claim 25, Koblisch and Ponzi do not disclose the diameters of the various components of the medical device. However, these parameters are deemed matters of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation, in determining optimum results. As to claim 40, the deflectable tip (18) is considered to be passively deflectable relative to the second portion and the thru lumen tubing (42) has an outer wall as shown in Figure 8A. As shown in Figure 3, the outer layer of the shaft along the first portion (504) is of uniform thickness and has an inner wall which forms the single shaft lumen positioned about the thru lumen tubing (42) and the manipulator wire (132 or 134) where the manipulator wire is advanceable and retractable between an inner wall of the outer layer and an outer wall of the thru lumen tubing. Figure 8A shows the outer layer along the second portion of the shaft where the outer layer forms the first lumen portion and the second lumen portion. The transition tubing (536) is positioned within the second lumen portion and extends between a proximal end of the second portion to a point along the second portion of the shaft as shown in Figure 3.

13. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koblisch and Ponzi as applied to claim 26 above, and further in view of Stewart et al.

Art Unit: 3767

Koblish and Ponzi disclose the invention substantially as claimed as discussed above. Even though Koblish teaches in paragraph [0048] that the polyether block amide outer layer may contain wire braids to provide torsional stiffness to the shaft, Koblish and Ponzi are silent on the outer layer including a stainless steel braiding and having a durometer reading of 72D along the first portion and being non-braided and having a durometer reading of 40D along the second portion. In Figure 15, Stewart et al show the outer layer of a medical device having a first portion (22) made of a high durometer (such as 72D) polyether block amide with a stainless steel braiding and a second non-braided portion and teach that the braiding provided reinforcement to the first portion. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the first portion of the outer layer of Koblish with a high durometer (such as 72D) polyether block amide with a stainless steel braiding as taught by Stewart et al as both Koblish and Stewart et al disclose devices having a deflectable second portion and Stewart et al teach that it would be advantageous to reinforce the first portion to allow for the proper deflection of the second portion when it is being used in a surgical procedure. As to the limitation of the second portion having a durometer reading of 40D, in lines 31-63 of column 16, Stewart et al teach that the second portion (30) is made to be sufficiently resilient or flexible and that material modifications can be made to suit the particular needs of the user. Therefore, the parameter of the durometer reading of the second portion is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

14. Claim 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish, Ponzi, and Stewart et al as applied to claim 27 above, and further in view of Hobot et al.

Koblish, Ponzi, and Stewart et al disclose the invention substantially as claimed as discussed above. Even though Koblish teaches a deflectable tip formed of a radio opaque and echo-genic polyether block amide material, Koblish is silent on the polyether block amide material being loaded with jet milled tungsten carbide and having a durometer reading of 35D. Hobot et al disclose a medical device having a deflectable tip (24) made of a polyether block amide material loaded with jet milled tungsten carbide and having a durometer reading of 35D. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the polyether block amide tip of Koblish with jet milled tungsten carbide and a durometer reading of 35D as taught by Hobot et al as both Koblish and Hobot et al teach advancing a medical device in blood vessels and Hobot et al teach that it is beneficial to have a tip that allow the distal end of the medical device to be seen by the user as it is advanced through the blood vessels.

15. Claims 30-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koblish, Ponzi, Stewart et al, and Hobot et al as applied to claim 29 above, and further in view of Truckai.

Koblish, Ponzi, Stewart et al, and Hobot et al disclose the invention substantially as claimed as discussed above. However, Koblish does not disclose the transition tubing being formed of a polyimide material having a durometer reading of 86D. In

Figure 2, Truckai shows a steerable medical device having a polyimide transition tubing (58) through which a manipulator wire extends. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the transition tubing of Koblisch from a polyimide material as taught by Truckai as both Koblisch and Truckai disclose steerable devices having a transition tubing through which a manipulator wire extends and Truckai teaches that it would be advantageous to make the transition tubing from polyimide to provide lateral and torsional stiffness to the deflectable tip. As to the limitation of the polyimide material having a durometer reading of 86D, the parameter of the durometer reading is deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. As to the limitation of the diameters of the compressible members in claim 35, to the limitation of the diameters of the various components of the medical device in claims 36 and 37, and to the limitation of the transition tubing having a length of approximately one inch in claim 39, the parameters of diameter and length are deemed a matter of design choice, well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

#### ***Response to Arguments***

16. Applicant's arguments filed September 11 2006 have been fully considered but they are not persuasive. Koblisch does teach a deflectable tip (18) which extends distally from the second portion (502) between a proximal end and a distal tip, and has a tapered portion between the proximal end and the distal tip. In Figure 3, the deflectable

tip (18) extends from the second portion (502). A distal tip or tip electrode (102) extends from the deflectable tip (18). The deflectable tip (18) is therefore located between a proximal end and the distal tip (102). It is the distal tip (102) which is disclosed as being "composed of a suitably thermal conducive biocompatible material, such as, e.g., platinum/iridium, stainless steel, gold, or silver", not the deflectable tip (18). Furthermore, as seen in Figures 11A to 11C, the tip (18) is deflectable. As to applicant's arguments that Koblish does not disclose the deflectable tip (18) as having a tapered portion located between the proximal end and the distal tip, Figure 3 clearly shows the deflectable tip (18) with a tapered portion. The deflectable tip (18) does taper or become narrower as seen at the portion of the deflectable tip (18) which is adjacent to the tip electrode (102) in Figure 3.

### ***Conclusion***

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3767

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
BM

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

